IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION
CASE NO. 1:17-CV-00111

LLOYD BELL, Individually and As Executor of the Estate of BETTY WHITLEY BELL, Deceased, Plaintiff, v. AMERICAN INTERNATIONAL INDUSTRIES, et al., Defendants.	)	**NORTHWELL HEALTH, INC.'S RESPONSE IN OPPOSITION TO DEFENDANT AMERICAN INTERNATIONAL INDUSTRIES' MOTION TO VACATE THE PRELIMINARY PROTECTIVE ORDER OF SEPTEMBER 25, 2020, AND WHITTAKER, CLARK & DANIELS, INC.'S NOTICE OF JOINDER**

NORTHWELL HEALTH, INC.'S RESPONSE IN OPPOSITION TO DEFENDANT AMERICAN INTERNATIONAL INDUSTRIES' MOTION TO VACATE THE PRELIMINARY PROTECTIVE ORDER OF SEPTEMBER 25, 2020, AND WHITTAKER, CLARK & DANIELS, INC.'S NOTICE OF JOINDER

Northwell Health, Inc. ("Northwell") submits this Response in opposition to Defendant American International Industries' ("AII") Motion to Vacate the Preliminary Protective Order of September 25, 2020, and Whittaker, Clark & Daniels, Inc.'s ("WCD") Notice of Joinder (collectively, "Motion to Vacate"). Specifically, Northwell opposes AII's attempt to unjustifiably unmask and make public Plaintiff Betty Bell's ("Plaintiff") identity as one of the research subjects of a published academic medical study governed by well-defined confidentiality protections afforded by Northwell's Institutional Review Board ("IRB"). Indeed, despite the bedrock federal laws, regulations, and guidance protecting the identities and information of research subjects in IRB-approved studies, AII claims that its self-serving desire to be able to obtain litigation advantages and avoid litigation costs in separate matters outweigh all other interests. This position is not only entirely unfounded, but the Motion to Vacate—if granted—poses significant, far-

reaching, and dangerous consequences for foundational confidentiality and privacy protections in academic medical research.

For these reasons and those set forth below, the Court should deny the Motion to Vacate and maintain the Protective Order.

I. BACKGROUND

Dr. Jacqueline Moline ("Dr. Moline") is an employed physician at Northwell and is board-certified in internal and occupational medicine. *See* Affidavit of Dr. Jaqueline Moline ("Moline Affidavit"), Dkt. 264-1 at ¶ 2. In addition to other roles, Dr. Moline is the chairperson of the Department of Occupational Medicine, Epidemiology and Prevention at North Shore University Hospital, which is a part of Northwell. *Id.* at ¶ 3. She is also a professor of medicine at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell. *Id.* at ¶ 4. In 2019, Dr. Moline—along with Kristin Bevilacqua, MPH, Maya Alexandri, JD, and Ronald Gordon, Ph.D.—authored and published a peer-reviewed article entitled, "Mesothelioma Associated with the Use of Cosmetic Talc" ("Article"). *Id.* at ¶ 7.[1] The Article was based on a research study involving the authors' analysis of records associated with thirty-three individuals with malignant mesothelioma who the authors' believed had no known asbestos exposure other than to cosmetic talcum powder ("Research Study"). *Id.* at ¶ 8. The Article's conclusion is that exposure to asbestos-contaminated talcum powders can cause mesothelioma and that clinicians should elicit a history of talcum powder usage in all patients presenting with mesothelioma. *Id.* at ¶ 9.

Prior to conducting the Research Study and drafting the Article, Dr. Moline sought and secured approval from Northwell's Human Research Protection Program ("HRPP") through its

[1] Throughout its briefing surrounding the Motion to Vacate, AII attacks the merits of the Article and Dr. Moline's associated research and conclusions. Northwell has not in this matter—and does not here—take a position as to those specific arguments.

Institutional Review Board ("IRB"). *Id.* at ¶ 10. Northwell's HRPP supports, facilitates, and promotes the ethical and safe conduct of research involving human subjects at Northwell. *Id.* at ¶ 11. The Northwell IRB is an independent research ethics review board—mandated by law and applicable regulations—and consists of healthcare professionals, scientists, and local community members. *Id.* at ¶ 12. The IRB serves to protect research participants' rights and welfare before and during research studies. *Id.* at ¶ 14. Specifically, IRBs are intended to ensure the protection of research subjects' privacy and confidentiality rights, including—most fundamentally—their identities and protected health information ("PHI"). *Id.* at ¶ 15; 45 C.F.R. § 46.111.

In the application for approval from the Northwell IRB for the Research Study and publication of the Article, Dr. Moline represented that (1) she took confidentiality seriously and would take extensive measures to protect the participants' identities; (2) no patient identifiers would be included in research-related summaries; (3) all PHI included in her review and the Article would be de-identified; (4) and the PHI would be stored in Northwell's secure database. *Id.* at ¶ 16. Additionally, in applying for approval, Dr. Moline sought and obtained a waiver of the informed consent requirements under 45 C.F.R. § 46.116. *See* **Exhibit A.**

As a result of these and other representations about the Research Study, Norwell's IRB granted approval on March 23, 2018. Moline Affidavit, at ¶ 17. In so doing, the IRB approval stated that Dr. Moline's Research Study met the criteria outlined in 45 C.F.R. § 46.110 and 21 C.F.R. § 56.110, which relate to expedited review and are part of regulations that stringently require research subject privacy and confidentiality. *Id.* at ¶ 18. Indeed, the IRB approval was specifically based on the fact that Dr. Moline's Research Study contained adequate provisions to protect and maintain the confidentiality of data and research participants. *Id.* at ¶ 19. The IRB approval also specifically directed Dr. Moline that research must be conducted in accordance with,

inter alia, 45 C.F.R. § 46 and the Health Insurance Portability and Accountability Act ("HIPAA"). *Id.* at ¶ 20.

Dr. Moline's Article was researched and published consistent with Northwell's IRB processes, as directed by the Federal Policy for the Protection of Human Subjects, 45 C.F.R. Part 46, Subpart A ("The Common Rule"). The Common Rule is well-established federal policy aimed at protecting the safety, privacy, and confidentiality of research subjects. It imposes a series of requirements on institutions engaging in human subject research, which is subject to regulation by applicable federal agencies, including the U.S. Department of Health and Human Services ("HHS"). *See* 45 C.F.R. § 46.101. Following the IRB approval in March 2018 and throughout the Article's research and publication process, Dr. Moline protected the research subjects' privacy and confidentiality. Moline Affidavit, at ¶ 21. Specifically, she did not disclose or otherwise reveal the research subjects' identities, as required by Northwell's IRB and applicable laws and regulations. *Id.* at ¶ 22. Indeed, Dr. Moline has not disclosed the identities of the research subjects in the Article. *See id.* at ¶ 23. Dr. Moline's refusal to identify Plaintiff's status as a research subject was based on IRB, privacy, and confidentiality standards surrounding research studies. *Id.* at ¶ 24.

II. PROCEDURAL HISTORY

On August 20, 2020, AII served Northwell with a subpoena. AII also provided Northwell with a narrow HIPAA authorization form ("HIPAA Authorization") that Plaintiff's husband completed on November 22, 2019 as the representative of Plaintiff's estate for purposes of the present litigation. Dkt. No. 179-6. The HIPAA Authorization authorized its recipients to disclose certain documents containing Plaintiff's PHI, including her medical records. *Id.*

In response to the subpoena, Northwell's previous counsel produced a partially redacted list of the thirty-three individuals that engaged in the research underlying the Article ("Northwell

Document"). The names of every individual that participated in the Research Study were redacted, except for that of the Plaintiff. The production of the Northwell Document led to several motions and related briefing concerning whether a protective order was required to prohibit the disclosure and use of the Northwell Document. *See* Dkt. Nos. 168, 179, 188, 197, 265, 274, 283, 316, 330, 334.

On September 25, 2020, the Magistrate Judge orally entered a protective order ("Protective Order") barring discovery into the identities of thirty-two of the thirty-three participants in Dr. Moline's research study. However, the Magistrate Judge's order allowed for discovery in this case regarding Plaintiff's inclusion in Dr. Moline's research study with that information designated as confidential and sealed. Dkt. No. 274-8 at 96:25, 97:1–10. The Magistrate Judge noted that allowing the use of the Northwell Document—solely in this case—was based on the Plaintiff having "put the matter at issue" and having "retained Dr. Moline as the expert in the case." *Id*. at 96:11–20.

On December 23, 2020, Northwell filed a Motion to Intervene and Extend Protective Order, seeking to prevent Defendants' counsels from questioning Dr. Moline about any linkage between Plaintiff and the Research Study. Dkt. Nos. 258, 265. On February 25, 2021, the Magistrate Judge denied Northwell's Motion to Intervene. Dkt. No. 309. Northwell filed an Objection, Dkt. No. 316, but the Court affirmed the Magistrate Judge's Order. Dkt. No. 350. Subsequently, the Court granted AII's motion for summary judgment and judgment was entered in this case. Dkt. Nos. 361, 364, 365, 366. AII then filed the present Motion to Vacate. Dkt. No. 368. WCD filed a joinder in AII's Motion to Vacate on October 13, 2021. Dkt. No. 373. Plaintiff filed a response to the Motion to Vacate on October 20, 2021. Dkt. No. 377.

III. ARGUMENT

AII seeks to vacate the Protective Order and make public record the Northwell Document, which would reveal Plaintiff as a participant in the Research Study underlying the Article. This request represents a dramatic departure from the narrowly tailored use of the Northwell Document that the Magistrate Judge permitted through the Protective Order. Notwithstanding that this action is concluded, AII seeks to permanently unmask Plaintiff as the subject of a confidential research study, and to allow itself—or, indeed, any member of the public—to use that confidential information in an ungoverned fashion and for any and all purposes it sees fit.

The thrust of AII's argument is that the Court should grant its Motion to Vacate because the Northwell Document is a judicial record and no countervailing interests outweigh the public's interest in the document. In denying the existence of countervailing interests to its own in using the Northwell Document in other litigation—and however else it sees fit—AII asserts that the Research Study is not human subject research and, therefore, is not subject to The Common Rule or protected by the confidentiality and privacy concerns applicable to human subject research.

For the reasons detailed below, none of AII's arguments nullify the Research Study's classification as human subject research subject to the Common Rule. Moreover, if the Court were to grant the Motion to Vacate, such a ruling would effectively gut the confidentiality and privacy guarantees inherent in IRB-related studies and run counter to well-established federal requirements. As such, the Court should deny the Motion to Vacate and protect the identities of participants in human subject research.

A. The Northwell Document is Not a Judicial Record and AII Has Not Shown Good Cause to Vacate the Protective Order.

The Fourth Circuit has held that judicial records are only records which "'play a role in the adjudicative process, or adjudicate substantive rights.'" *United States* ex rel. *Thomas v. Duke*

University, 2018 WL 4211375, *3 (September 4, 2018); *In re Policy Management Systems Corp.* 67 F3d 296, 1995 WL 541623 *4 (4th Cir. 1995). "[T]o the extent the court does not rely on [a document] in reaching its decision," the document is not a judicial record and "no right of access applies." *Hunter v. Town of Mocksville,* 961 F. Supp. 2d 803, 806 (M.D.N.C. 2013)); *see also United States v. Moussaoui*, 65 F. App'x 881, 889 (4th Cir. 2003) (observing some court-filed documents "may not qualify as 'judicial records' at all"). The Fourth Circuit has held that "the mere filing of a document with a court does not render the document judicial." *In re Policy Mgt. Sys. Corp.,* 67 F.3d 296, 1995 WL 541623, at *4 (4th Cir. 1995); *See also Kinetic Concepts, Inc. v. Convatec, Inc.,* 2010 WL 1418312 at *7 (M.D.N.C. April 2, 2010) (acknowledging "*In re Policy Management* as 'highly persuasive' authority for the position that no public access right attaches to court-filed documents related to discovery disputes.") (quoting *United States v. Blowers,* 2005 WL 3830634, at *4 (W.D.N.C. Oct.17, 2005))).

As a threshold matter, and contrary to AII's assertion that this issue is undisputed, the Northwell Document is not a judicial record. AII argues that the Northwell Document is a judicial record because "[i]t was attached to AII's Opposition to Northwell Health's Objections and Appeal" and "the subject of numerous motions." Dkt. No. 369, at 12. However, attaching a document to a filing as an exhibit—or mentioning a document in "numerous motions"—does not make that document a judicial record. *See United States* ex rel. *Thomas*, 2018 WL 4211375, at *4 ("The Court has not identified any Fourth Circuit decision classifying exhibits to a motion to seal as 'judicial records.' However, courts in this circuit have found that documents filed to facilitate protective orders and other discovery motions do not qualify as judicial records.").

The Court did not rely on the Northwell Document to adjudicate any substantive right in this case, nor was the Northwell Document central to any issue in this case. The document was

never used, discussed, or relied upon for any dispositive motions. *See Guessford v. Pa. Nat'l Mut. Casualty INS. Co.,* 2014 WL 12594127, at *2 (M.D.N.C. Sept. 30, 2014) (finding documents related to motions for summary judgment, sanctions, and *in limine* to be "judicial records" because "[e]ach set of documents was filed in connection with either a dispositive or non-dispositive motion, and each motion was filed with the objective of obtaining judicial action (namely, the granting of a motion *other than a motion to seal*)" (emphasis added)). Even when deciding the issue of whether the document should be protected under seal, the Court did not rely on the document itself. Because the Court did not rely on the document to adjudicate any substantive rights or dispositive motions, and did not rely on the document to reach any judicial decisions in this case, the document is not a judicial record.

Because the Northwell Document is not a judicial record, the proper standard for determining whether the Court should vacate the Protective Order is the "good cause" standard articulated in Federal Rule of Civil Procedure 26(c). *BASF Agro B.V. v. Makhteshim Agan of N. Am., Inc.,* 2013 WL 12178583, at *4 (M.D.N.C. Sept. 30, 2013) (holding that the exhibits at issue were "not judicial records because they were filed with the objective of providing information, not obtaining judicial action or relief."). Specifically, the burden is on the party requesting the modification of the protective order to show good cause that the modification is warranted. *SmithKline Beecham Corp. v. Synthon Pharmaceuticals, Ltd.,* 210 F.R.D. 163, 166 (M.D.N.C. 2002) (denying Plaintiff's motion to modify the protective order in order to use the materials in other litigation, but, stating that, "[n]evertheless, prudential concerns convince the Court that a motion to modify a protective order in order to use material in other litigation should, in most cases, be the last resort of a party, not the first.").

AII requests that this Court vacate the Protective Order and make the identity of Plaintiff—a participant in human subject research—a matter of public record. AII seeks to do so for the purpose of making the information available for its and other defendants' potential use in separate and unrelated litigation across the country. Dkt. No. 369 at 17; 24. AII also suggests that using Plaintiff's identity as a research subject will save on litigation costs. Dkt. No. 369 at 17. However, AII has not demonstrated how circumstances that warranted the initial entering of the Protective Order in this case have changed such that AII's planned and ungoverned usage of this information is proper. Indeed, as set forth extensively below, Plaintiff's identity remains protected under The Common Rule and the confidentiality and privacy protections inherent in HIPAA still apply to this case. AII's private interests in seeking litigation advantages over unrelated plaintiffs in unrelated cases and in saving on litigation costs does not establish good cause for ignoring the significant requirements of bedrock federal laws, regulations, and privacy protections applicable here.

B. Northwell's Significant Interests in Protecting the Identities of Human Research Subjects in Northwell IRB-Approved Research Far Outweigh AII's Private Interests.

Even if the Court determines that the Northwell Document is a judicial record, which Northwell strongly disputes, the countervailing interests in protecting the privacy of participants in human subject research and complying with federal laws and regulations far outweigh AII's purported interests.

Institutions like Northwell that are engaged in human subject research are required to follow the policies and processes set forth within The Common Rule as part of the terms of the research institution's Federalwide Assurance ("FWA"). *See* 45 C.F.R. § 46.103(a). The FWA is a formal agreement established with the Office for Human Research Protections ("OHRP"), which is an office within HHS. *Id*. Through the FWA that it submitted to OHRP, Northwell has expressly affirmed to the federal government that it will protect the privacy and confidential PHI of all

individuals involved in human subject research and that it will comply with The Common Rule and all of the terms of the FWA.

Although Dr. Moline did not have direct person-to-person contact with patients in researching the Article, her analysis of identifiable medical records in preparing her research findings qualified as human subject research for purposes of The Common Rule. *See* 45 C.F.R. §46.102 (defining human subject research as including research in which a researcher obtains, uses, studies, or analyzes identifiable private information, such as a medical record). Accordingly, to conform to The Common Rule policies, Northwell's IRB required Dr. Moline to submit to Northwell a research proposal demonstrating, among other requirements, that there were adequate protections in place to protect the privacy of the research subjects and to maintain the confidentiality of the patients' health data. Moline Affidavit at ¶¶ 16-19; 45 C.F.R. § 46.111.

Northwell's IRB approved Dr. Moline's research study because it met the criteria outlined in 45 C.F.R. § 46.110 and 21 C.F.R. § 56.110, which relate to expedited review and are part of regulations that stringently require research subject privacy and confidentiality. *Id.* at ¶ 18. Indeed, the IRB approval was specifically based on the fact that Dr. Moline's research study contained adequate provisions to protect and maintain the confidentiality of data and research participants. *Id.* at ¶ 19. The IRB approval also specifically directed Dr. Moline that research must be conducted in accordance with, *inter alia*, 45 C.F.R. § 46 and HIPAA. *Id.* at ¶ 20. In compliance with Northwell's IRB and applicable laws and regulations, Dr. Moline has protected the research subjects' privacy and confidentiality throughout the research and publication process and has not identified any of the individuals involved in the Research Study. *Id.* at ¶ 21-22.

While disclosure of the identity of a participant in human subject research when that individual initiates litigation is itself improper, AII now seeks a dramatically broader disclosure

than the one afforded to it in this case. AII argues that it is in the public interest to release the identity of a participant in human subject research so that the author of the research may be confronted with questions concerning the research's accuracy and reliability. Dkt. No. 369 at 16. However, such a position rings hollow. Congress and the executive agencies to which it has granted authority have clearly expressed, through both federal laws and regulations, the paramount importance of the privacy and confidentiality of participants in human subject research. AII's reasoning in its Motion Vacate—which, if adopted by the Court, is potentially applicable to all research studies—could provide a bases for wide scale circumvention of The Common Rule and related congressional intent. Moreover, denying the Motion to Vacate and applying the protections inherent in The Common Rule do not preclude AII or any other defendant across the country from questioning Dr. Moline about her methods and the reliability of the Research Study.

In a meager attempt to frame its purported interests, AII asserts that its request to disclose Plaintiff's identity is not intended to promote a public scandal or gain an unfair business advantage. Dkt No. 369 at 14. However, AII is asking this Court to contravene federal law and regulations so that it may have an advantage in other asbestos litigation. Indeed, the entire purpose of AII's request to make the Northwell Document public record is so that it, and other companies involved in asbestos litigation, may use the Northwell Document in litigation. *See* Dkt. No. 369, at 17 ("Litigation and related costs have forced some cosmetics sellers, including AII to withdraw talcum powder from the market….AII and other defendants continue to be confronted with Moline's Article in litigation."). In short, AII requests that the Northwell Document be made public record for its own benefit, and the benefit of other similarly situated companies involved in asbestos litigation. Such self-serving interests of companies desiring a strategic litigation advantage and to save on litigation costs simply do not outweigh the significant interests that the

medical research community has in maintaining the privacy and confidentiality of participants in human subject research and the dictates of The Common Rule.

C. Making the Identities of Participants in Human Subject Research Public Record Will Have a Chilling Effect on Medical Research.

The IRB review process involves a balance of risks that the subjects of that research may be harmed by unexpected or inadvertent release of their information, with the benefits that the research may provide to the public. As such, Northwell has a significant interest in protecting the anonymity of research participants. Medical research studies are crucial to the growth of modern medicine and to understanding and eliminating diseases. If researchers and research institutions that are non-parties to litigation are required to disclose the identity of anonymous research subjects, the result would be a chilling effect on the IRB process and the medical community, including the potential for impeding the development of life-saving medical breakthroughs. To make that disclosure a matter of public record that can be used in litigation across the nation would be potentially disastrous for the medical community's ability to recruit individuals for human subject research.

Specifically, when individuals agree to participate in human subject research, they do so with the understanding that a rigorous process has been undertaken to guarantee that their privacy will be protected in compliance with federal laws and regulations. This understanding is supported by decades of medical research that has adhered to The Common Rule's requirements. Forcing the disclosure of the identities of research subjects so that those identities can be weaponized for litigation purposes—including in litigation that does not involve the particular research subject—would significantly dissuade individuals from agreeing to participate in human subject research. Such an effect would be due in significant part to the fact that both the individual and the research institution would lose all abilities to determine and/or control how a research subject's PHI is used

beyond the research study. Moreover, individuals and research institutions alike would be forced to weigh the value of potentially life-saving research proposals with undefined and ungoverned litigation risks.

In light of such concerns, courts regularly protect the confidentiality of the research process, affording special discovery protections to research scholars and their research publications. *See, e.g., Cusumano v. Microsoft Corp.,* 162 F.3d 708 (1st Cir. 1998) (holding First Amendment considerations justify protecting academics engaged in scholarly research so as to prevent a chilling effect on the ability of researchers to gather and disseminate information); *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation,* 249 F.R.D. 8, 13–14 (D.Mass. 2008) (finding chilling effects would occur if the identity of anonymous peer reviewers were required to be disclosed in product liability discovery). Some of these courts have noted the particular First Amendment harm to the free flow of information—essential to the research process—when researchers are ordered to violate their assurances of confidentiality. *Id.* at 716–717. Courts have also long recognized that this confidentiality is often essential to the ability of researchers to obtain data. *Richards of Rockford, Inc. v. Pacific Gas & Electric Co.,* 71 F.R.D. 388, 390 (N.D.Cal.1976); *Lampshire v. Proctor & Gamble Co.*, 94 F.R.D. 58 (N.D.Ga.1982).

Protecting the free flow of information in human subject research not only benefits Northwell, but it also serves a compelling societal interest that is jeopardized when confidentiality is breached or eviscerated. Accordingly, AII's request to make Plaintiff's identity public record has far reaching implications beyond this case and it should be denied.

D. The Common Rule Applies to the Research Study, Which Involved Human Subject Research.

AII argues that the Research Study is not human subject research because: (1) Dr. Moline did not obtain informed consent from Plaintiff; (2) the Research Study was not conducted by, or on behalf of, the federal government or any state agency; and (3) Plaintiff is deceased. *See* Dkt. No. 369. AII incorrectly states that Dr. Moline "did not comply with the mandatory requisites of any human research statute by failing to obtain consent from Ms. Bell or an authorized representative." *Id.* at 19. While it is correct that individuals participating in human subject research ordinarily must provide informed consent, this requirement can be waived by the IRB in cases of expedited review. 45 C.F.R. §46.117(c)(1). Dr. Moline sought and secured a waiver of the informed consent requirement from the Northwell IRB. *See* **Exhibit A**. Furthermore, in approving Dr. Moline's research proposal through the IRB informed consent waiver, the IRB had to establish that her proposal presented "no more than minimal risk of harm" to the research subjects, including a minimal risk of harm resulting from a breach of confidentiality. 45 C.F.R. § 46.117(c)(1)(ii). As such, permitting the identity of *any* individuals involved in the Research Study to become public record would be detrimental, and run completely counter, to the confidentiality guarantees of Northwell's IRB.

AII's argument that the Research Study underlying the Article is not subject to The Common Rule's requirements because it "was not conducted by, or on behalf of, the federal government or any state agency" is also incorrect. Dkt. No. 369 at 19. As underscored above, institutions like Northwell that engage in human subject research subject to The Common Rule have to provide a "Federalwide Assurance" to the Office of Human Research Protections that they will comply with the requirements of The Common Rule. 45 CFR 46.103(a). As part of submitting a FWA, an institution can, and many do, elect to apply the Common Rule requirements to <u>*all*</u>

human subject research, regardless of the source of support or funding for that research. Based on its HRPP policies, Northwell has indicated in its FWA to the federal government that The Common Rule will apply to all of its human subject research.[2] Northwell's HRPP policies state, in relevant part, that:

> Northwell Health has a Federal Wide Assurance (FWA) to cover all of its facilities, which assures the Department of Health and Human Services (DHHS) that it will follow procedures to assure the protection of all human subjects involved in research projects. The assurance is a formal agreement between the Office for Human Research Protections (OHRP) and the authorized Institutional Official for Northwell. This assurance applies to all research involving human subjects, regardless of source of funding or support, conducted at Northwell Health, as well as to research conducted elsewhere by physicians, students, staff, or other representatives of Northwell in connection with their institutional responsibilities.

Thus, since The Common Rule applies to all Northwell research regardless of funding source, AII's argument that the human subject research was not conducted by, or on behalf of, the federal government has no bearing on whether the Common Rule applies. Northwell, through the FWA, explicitly guarantees to the federal government that it will protect the privacy of research subjects and maintain the confidentiality of their PHI, which fundamentally encompasses their identities.

Similar to AII's other arguments, its assertion that the Research Study is no longer human subject research bound by the privacy protections of The Common Rule because of Plaintiff's death is incorrect. Dr. Moline did not apply for and secure IRB approval surrounding a research study involving Plaintiff alone. Instead, she did so for a research study involving thirty-three individuals, at least twenty-three of whom were living at the time of her study. Dkt. Nos. 265-1, 274-1. The confidentiality protections required by Northwell's IRB and Dr. Moline's confidentiality guarantees necessary to secure IRB approval were for the entire Research Study,

[2] *See* NORTHWELL HEALTH HUMAN RESEARCH PROTECTION PROGRAM POLICIES AND PROCEDURES, at 11, https://www.northwell.edu/sites/northwell.edu/files/2021-05/HRPP-Policies-and-Procedures-FINAL-2021.pdf.

and not for any one particular individual. *See* Dkt. No. 265-1. This reality is consistent with the fact that an IRB reviews unified research proposals holistically and its approvals are correspondingly applied holistically to the research studies themselves—the protocols do not apply to certain research subjects in some situations, and to other research subjects in other situations.[3] *See* 45 C.F.R. § 46.101.

The process for obtaining IRB expedited review requires an acknowledgement that the risk to research participants' privacy interests must be no more than minimal. 45 C.F.R. § 46.110. In this Court's February 25, 2021 Order, the Magistrate Judge noted that there exists a critical concern that expansive inquiries into research subject identities could result in the IRB expedited review process becoming "essentially a dead letter, forcing all research into a slower, costlier process for approval." Dkt. No. 309 at 7. Notwithstanding the chilling effects this reality would create, this Court was able to draw a narrow exception for purposes of this litigation; namely, because Plaintiff initiated this lawsuit and retained Dr. Moline as an expert witness, her participation in Dr. Moline's study was germane "for purposes of this case," and Plaintiff could be deemed as consenting to a disclosure of her participation in the Research Study for purposes of this case. *Id*., at 7–8 (citing *Farnsworth v. Proctor & Gamble Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985) (acknowledging that "'disclosure of the names of addresses of [nonconsenting] research participants could seriously damage' voluntary reporting" and hinder scientific progress)). AII's Motion to Vacate seeks disclosure of PHI that goes well-beyond the Magistrate Judge's narrow exception applicable to

[3] *See* NIH, "Guidelines for Reviewers: Protections for Human Subjects Review Criterion," https://grants.nih.gov/grants/peer/guidelines_general/Guidelines_for_the_Review_of_the_Human_Subjects.pdf, at 4 (March 18, 2019). *See also* Univ. of Pitt., "Research on Deceased Individuals," https://www.hrpo.pitt.edu/policies-and-procedures/research-deceased-individuals ("Research involving deceased individuals … does not require IRB oversight unless the research involves both living and deceased individuals.").

this litigation and exemplifies the type of expansive inquiry that the Magistrate Judge acknowledged as a threat to research-related privacy and confidentiality.

E. Vacating the Protective Order Would Violate the Purpose of HIPAA and Exceed the HIPAA Authorization.

As the Court is well-aware, HIPAA is a federal law that protects the privacy and security of individuals' PHI and applies to covered entities, such as Northwell. HIPAA's Privacy Rule sets national standards for the protection of PHI, which that Rule defines as all "individually identifiable health information." 45 C.F.R. § 160.103. Not only does HIPAA protect PHI associated with living individuals, it also applies to PHI associated with deceased individuals. 45 C.F.R. § 164.502(f). Specifically, the Privacy Rule applies to a decedent's PHI for fifty (50) years following the individual's date of death. *Id.* Throughout this period, the decedent's personal representative is able to exercise the rights of the decedent under the Privacy Rule with regard to the decedent's PHI. Pursuant to HIPAA's Privacy Rule, unless a regulatory exception is met (and none is here), covered entities are only permitted to disclose PHI for both living and deceased individuals pursuant to a valid HIPAA authorization and in accordance with the parameters of that authorization. 45 C.F.R. § 164.508(a)(1).

The Northwell Document disclosing Plaintiff's identity as a subject of the Research Study was provided to AII pursuant to a narrow HIPAA Authorization that Plaintiff's husband completed as the representative of Plaintiff's estate. Dkt. No. 179-6. By its terms, the HIPAA Authorization was provided by the Plaintiff's husband "for the purpose of review and evaluation in connection with [the] legal claim" in Plaintiff's case and narrowly authorizes the release of certain categories of Plaintiff's PHI *solely to* Pike Photography, Inc., which is presumably a service used by Defendants in this matter during the course of discovery. *See id.* Nowhere in the HIPAA Authorization does it authorize the disclosure of Plaintiff's PHI beyond this litigation or to entities

other than Pike Photography, Inc., for use outside of these proceedings, and/or to the broader public. Northwell produced the Northwell Document based on the language and parameters set forth in the HIPAA Authorization, and the Protective Order was entered in this case to, *inter alia*, keep confidential such PHI.

AII's Motion to Vacate effectively seeks an end run around HIPAA's privacy guarantees and the HIPAA Authorization. In other words, AII's Motion to Vacate is a thinly veiled attempt to use the Court's procedural processes to dramatically expand the release of PHI in a manner that was never contemplated or authorized. Not only is such an attempt improper pursuant to HIPAA's privacy guarantees and the HIPAA Authorization, but, if allowed, presents potentially dangerous precedent whereby parties—as here—can use a narrow HIPAA authorization as a stepping stone to a much broader and uncontrolled release of PHI.

Judgment in this case has now been issued, and any authorization for the release of PHI Plaintiff may be deemed to have given for purposes of this case has likewise run. Yet, Defendants now seek permission to use Plaintiff's confidential information in perpetuity, for any purpose they—and any third party—see fit. This Court should resist this effort by Defendants to effectuate a wholesale evisceration of Plaintiff's and Northwell's vested privacy interests pursuant to The Common Rule, the IRB process, and the purpose of HIPAA.

IV. CONCLUSION

For the foregoing reasons, Northwell respectfully requests that the Court deny AII's Motion to Vacate and maintain the Protective Order.

This the 29th day of June, 2022.

/s/ John H. Lawrence
John H. Lawrence
N.C. State Bar No. 45462
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560
Telephone: (919) 466-1112
john.lawrence@klgates.com

ATTORNEY FOR NORTHWELL

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 29, 2022, the foregoing Memorandum of Law was filed via ECF filing, which will serve all counsel of record in the above-referenced matter.

This the 29th day of June, 2022.

/s/ John H. Lawrence
John H. Lawrence
N.C. State Bar No. 45462
430 Davis Drive, Suite 400
Morrisville, NC 27560
Telephone: (919) 466-1112
john.lawrence@klgates.com

ATTORNEY FOR NORTHWELL

CERTIFICATE OF WORD COUNT

This brief complies with Local Rule 7.3(d)(1)'s word count limitation. The word count feature on Microsoft Word states that the word count of the counted potions of this brief is 5,818, within the 6,250 word limit.

/s/ John H. Lawrence
John H. Lawrence
N.C. State Bar No. 45462
430 Davis Drive, Suite 400
Morrisville, NC 27560
Telephone: (919) 466-1112
john.lawrence@klgates.com

ATTORNEY FOR NORTHWELL